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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,168	02/22/2005	Christopher R. Yonan	06056-0313US1	5885
23973	7590	08/30/2007		
DRINKER BIDDLE & REATH ATTN: INTELLECTUAL PROPERTY GROUP ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996			EXAMINER HANLEY, SUSAN MARIE	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 08/30/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,168	Applicant(s) YONAN ET AL.	
	Examiner Susan Hanley	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____</p> |
|---|--|

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AILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 5/2/07 is acknowledged.

The traversal is on the ground(s) that the cited patent does not disclose the special technical feature. This argument is persuasive and the restriction requirement is withdrawn.

Claims 1-17 are presented for examination.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 6, 7, 14 and 15 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Bayramoglu et al. (July, 2002).

Bayramoglu discloses membranes that are conjugated to Procion Brown MX-5BR (synonym for Reactive Brown 10; see Registry print out for this compound) and exposed to lysozyme which binds to the dye ligands. Bayramoglu also discloses that the membrane-immobilized dye also comprises iron and copper metal ions (abstract). This disclosure meets the indicated claimed limitations because Bayramoglu teaches the three components of the composition of claims 6 and 7: a protein is bound to a membrane comprising immobilized dye ligands of Reactive Brown 10. The instant claims do not exclude immobilization of the dye on the membrane. The claims are "open" (comprising) which allows for unnamed components in addition to those that are claimed.

This reference meets the limitations of claims 14 and 15 because Bayramoglu teaches that the membrane and the dye were brought together as separate materials to make the dye-immobilized membrane. A kit is a collection of articles. The gathering of these articles by Bayramoglu meets the limitations of a kit. Bayramoglu teaches that the pHEMA/chitosan membrane

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binds lysozyme at a low level. However, the disclosure that the membrane taught by Bayramoglu binds even one molecule of lysozyme meets the limitation that the membrane is capable of binding proteins.

The disclosure by the Registry database is a supporting reference and properly used in a rejection under of U.S.C. 102 since it describes the various synonyms for Reactive Brown 10. MPEP 2131.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alam (US 6,174,729) in view of Hopwood et al. (1973) and Miyagi et al. (1975; abstract only).

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Alam discloses a method for visualizing and quantitating a protein of unknown concentration on a membrane using a Coomassie stain and protein standards. The method comprises applying a protein solution to a support that is capable of binding the protein. The protein-binding membrane is nitrocellulose having a binding capacity for the standard reference protein, BSA, of at least $100 \mu\text{g}/\text{cm}^2$ (col. 5, lines 45-59). The spots of protein solution are proportional to the concentration of total protein in the solution that is applied to the membrane in the presence of a detergent, salt or acid (col. 6, lines 10-20). The standard protein, in various concentrations via serial dilutions, is applied to the membrane as an internal standard. The internal standard can be pre-spotted (col. 8, lines 3-14). The standard protein is preferably BSA (col. 8, lines 50-55). A standard curve that plots spot diameter and concentration of the standard protein is constructed. The spotted membrane can be stained with any dye known to bind proteins to produce a visible spot. Alam teaches that Coomassie blue is a typical dye (col. 7, lines 43-57). The concentration of the unknown protein is determined after staining and comparison with the standard curve. The procedure is performed at room temperature (see Ex. 1). Alam also discloses a gathering of reagents including the standard BSA protein, the membrane and stain. Alam does not formally name the gathering of said reagents as a kit. However, a kit is simply a collection of reagents. Therefore, the disclosure of Alam meets the limitations of a kit.

Alam does not teach the use of a triazine dye such as Reactive Brown 10, as instantly claimed, as the staining agent and incubating the dichlorotriazine-stained protein-binding membrane with an aqueous alkaline solution and washing said stained membrane to remove the staining reagent.

Miyagi discloses that several Procion dyes (dichlorotriazine dyes, e.g., Procion Blue M-RS) were compared with Coomassie blue for their ability to stain human serum protein immobilized on

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filter paper or cellulose acetate. The dyes were effective for visualizing and determining protein concentration via optical density.

Hopwood discloses the ability of dichlorotriazine dyes to stain proteins and glycogen in tissues (abstract). The tested dyes included Red Brown which is a synonym for Reactive Brown 10 (see Registry printout). Hopwood discloses that dichlorotriazine dyes reacted with and cross-link proteins at pH 6.0 to 8.6 (p. 401, 2nd full paragraph). Said dyes can be visualized with the naked eyes (p. 394, under the heading "Histological findings").

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a triazine dye such as Reactive Brown 10 as the staining agent in the method of Alam. The ordinary artisan would have been motivated to do so because Alam teaches that any stain that is visible to the naked eye is suitable to stain the protein-spotted membranes in his method. The ordinary artisan would have known from Miyagi that dichlorotriazine dyes are suitable for staining, visualizing and quantitating proteins immobilized on membranes. Furthermore, Hopwood teaches that Procion dyes such as Reactive Brown 10 are suitable for staining and visualizing proteins in tissues. Hence, the ordinary artisan would have known that dichlorotriazine dyes, including reactive Brown 10, are suitable alternatives to Coomassie Blue for the purpose of staining, visualizing and quantitating proteins on protein-binding membranes in the method of Alam. As ruled recently,

Fact that claimed combination of elements was "obvious to try" might show that such combination was obvious under 35 U.S.C. §103, since, if there is design need or market pressure to solve problem, and there are finite number of identified, predictable solutions, person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation. KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007)

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In the instant case, dichlorotriazine dyes are one class of staining reagents known to stain proteins that are immobilized on membranes.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incubate the dichlorotriazine-stained protein-binding membrane with an aqueous alkaline solution and washing said stained membrane to remove the staining reagent. The ordinary artisan would have known from Hopwood that dichlorotriazine dyes can cross-link proteins at pH 6.0-8.0. The ordinary artisan would have known that this is desirable in order to obtain a stable bond between the dye and the protein. It is well within the purpose of the ordinary artisan to determine the most suitable pH in this range to effect cross-linking as well as to rinse the stained protein-bound membrane in order to accurately visualize the stained protein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Hanley
Patent Examiner
Art Unit 1651

SANDRA E. SAUCIER
PRIMARY EXAMINER

